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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/784,681 | 02/23/2004 | Chein-Shyong Su | U 015044-9 | 1963 |

140 7590 07/28/2005

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| EXAMINER | |
|---|---|
| VESTAL, REBECCA MICHELLE | |
| ART UNIT | PAPER NUMBER |
| 1753 | |

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/784,681 | SU ET AL. | |
| | Examiner | Art Unit | |
| | R. Michelle Vestal | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5-14,16-23 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-14,16-23 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of the amendment dated May 20, 2005, which papers have been placed of record in the file.

Claims 1-3, 5-14, 16, 19-23 and 27-29 are amended. Claims 4, 15 and 24-26 are canceled. Claims 30 and 31 are new. Claims 1-3, 5-14, 16-23 and 27-31 are pending and have been examined in this office action.

The drawings have been amended to overcome the previous objection.

All previous objections and rejections not set forth below have been withdrawn.

### *Response to Arguments*

Applicant's arguments regarding Bhullar have been fully considered but they are not persuasive. Applicant argues that Bhullar does not disclose a capillary inflow channel formed in the middle layer or an upper cover adhered to the middle layer. This allegation is not persuasive because Bhullar does disclose these features, as indicated in the current rejection of claim 1. Specifically, Bhullar discloses a middle insulating layer disposed on said electrode layers without covering said electrodes and said contact ports (Fig. 11, **114**), said middle insulating layer having a slot therein above said electrodes (Fig. 11, **140**) and an upper cover (Fig. 11, **122**) adhered to said middle

insulating layer (col. 9, lines 10-24) with a thin plate disposed on top of the upper cover (Fig. 11, **124**) and having an upwardly extended closed chamber therein containing said substances, said chamber being disposed above and in communication with one end of said slot (Fig. 10 or 11, **170**), said slot defining a capillary inflow channel (Fig. 11, **140**) to enable a sample of said substances to be rapidly introduced into and fill said electrode reaction area by capillary action upon contact with a front tip of said capillary inflow channel (col. 9, lines 25-26), said slot being configured to form said sample such that the sample does not extend beyond said chamber along said capillary inflow channel (col. 9, lines 26-30).

Applicant's arguments regarding claim 27 have been fully considered but they are not persuasive. Applicant argues that the combined references do not teach the added limitations to claim 27. This allegation is not persuasive because Nankai discloses a biosensor with a chamber (see for example fig. 4, 11) within an upper cover (fig. 4, 9) above and in communication with one end of a slot (fig. 4, 8) in a middle insulating layer (fig. 4, 7). The slot defines a capillary inflow channel such that sample can be rapidly introduced into and fill an electrode layer by capillary action upon contact wit the front tip of the capillary inflow channel (col. 5, lines 19-41). Nankai also discloses that the sample is configured not to travel beyond the chamber along the capillary inflow channel (col. 5, lines 24-29). Nankai does not disclose that the chamber is closed. Bhullar teaches a biosensor comprising an upwardly extended closed chamber (see for example fig. 11). It would have been obvious to include the step of

applying a surface cover layer above an upper cover to form a closed chamber above and in communication with the slot of Bhullar in the method of fabricating a biosensor of Nankai because the surface cover layer blocks exposure of the reagent/sample mixture to the surrounding environment, as taught by Bhullar (Col. 5, lines 36-40). This protection from contamination would help ensure more accurate and reliable measured results.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-14, 16-20, 22, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,488,828 to Bhullar et al. in view of U.S. Patent Number 5,120,420 to Nankai et al., referred to hereafter as "Bhullar" and "Nankai," respectively.

Regarding claims 1 and 31, Bhullar discloses an electrochemical biosensor (Col. 1, lines 5-6), comprising:

an insulating substrate (Fig. 11, **12**);

an electrode layer comprising a plurality of electrodes including a reference electrode and at least one other electrode (Fig. 11, **16** and **18**), and at least two contact ports adapted to connect to a measuring device, said electrode layer being disposed on said insulating substrate (Col. 3, lines 3-11);

a middle insulating layer disposed on said electrode layers without covering said electrodes and said contact ports (Fig. 11, **114**), said middle insulating layer having a slot therein above said electrodes (Fig. 11, **140**);

an active reaction layer having substances of reactant, reaction catalyst, mediator and surfactant (Fig. 11, **120**) spread on the surface of said electrodes defining an electrode reaction area; and

an upper cover (Fig. 10 or 11, **122**) adhered to said middle insulating layer (col. 9, lines 10-24) with a thin plate disposed on top of the upper cover (Fig. 11, **124**) and having an upwardly extended closed chamber therein containing said substances, said chamber being disposed above and in communication with one end of said slot (Fig. 10 or 11, **170**), said slot defining a capillary inflow channel (Fig. 11, **140** and col. 9, lines 25-26) to enable a sample of said substances to be rapidly introduced into and fill said electrode reaction area by capillary action upon contact with a front tip of said capillary inflow channel (col. 9, lines 25-26), said slot being configured to form said sample such that the sample does not extend beyond said chamber along said capillary inflow channel (col. 9, lines 26-30).

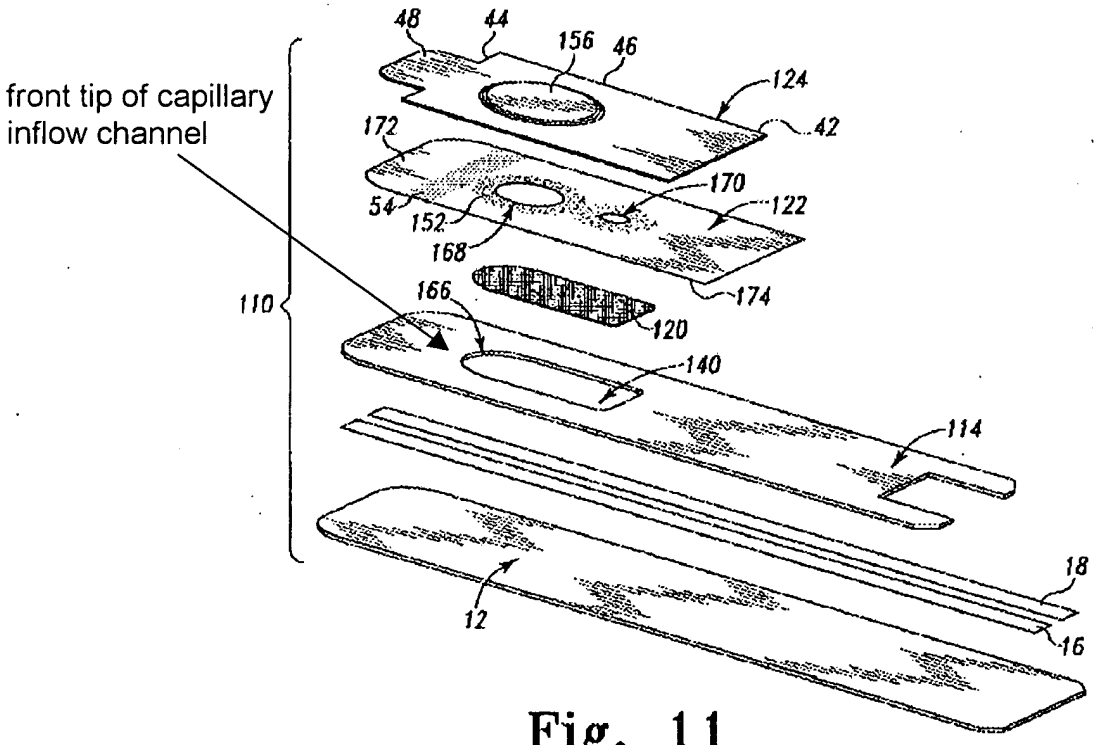


Fig. 11

Bhullar does not disclose expressly that a layer of electrically conductive wires is disposed on said insulating base plate with an electrode layer formed on said wires.

Nankai discloses an electrochemical biosensor comprising a layer of electrically conductive wires disposed on an insulating base plate and a layer of electrodes formed on said wires (Col. 4, lines 51-55). Nankai also teaches that the middle insulating layer can comprise a slot that is formed either contained in an interior portion of the insulating layer (see, for example, figs. 8 or 13, **7**) or from a side edge of the insulating layer (see for example, Figs. 4, 10 or 12, **7**).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the layer of electrically conductive wires of Nankai in the electrochemical biosensor of Bhullar because the conductive wires are useful for forming a good electrical contact with the measuring device or meter.

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the invention as specified in claim 1.

It is noted that, although this limitation is not claimed, a person of ordinary skill in the art would also find it obvious to modify the shape of the slot of Bhullar to extend to a side edge of the insulating layer of Nankai because such a slot allows the introduction of sample from a side edge of the biosensor. Nankai teaches that many shapes and configurations of the slot are known for various sampling and analysis applications (figs. 4, 8, 10, 12 and 13).

Bhullar discloses the limitations of claim 2, wherein said biosensor is a bi-electrode system comprising a working electrode and a reference electrode (Col. 3, lines 3-11).

Bhullar discloses the limitations of claim 3, wherein said biosensor is a tri-electrode system comprising a working electrode, a reference electrode and an auxiliary electrode (Col. 3, lines 3-11).

Bhullar discloses the limitations of claim 6, wherein the insulating substrate is made of material selected from the group consisting of polyester, polyimide, and polyvinylchloride (Col. 2, lines 32-35).

Bhullar discloses the limitations of claims 7 and 9-13, wherein said electrode layer or said layer of electrically conductive wires is made of silver, gold, carbon or platinum (Col. 2, lines 48-57).

Bhullar discloses the limitations of claims 14 and 16, wherein said reaction catalyst is a biocatalyst or enzyme (Table 1).

Bhullar discloses the limitations of claims 19 and 20, wherein the length and width of said slot is between 2 and 8 mm and between 0.5 and 5 mm, respectively (Col. 9, lines 26-30).

Bhullar discloses the limitations of claim 22, wherein sample can be detected when it is introduced above said working electrode and said auxiliary electrode (Col. 7, line 59-Col. 8, line 60).

Regarding claim 8, Bhullar discloses a biosensor comprising a reference electrode (Col. 3, lines 5-11).

Bhullar does not disclose expressly that the reference electrode comprises silver chloride.

Nankai discloses a biosensor, wherein said layer of electrically conductive wires is silver chloride (Col. 10, lines 8-17).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a reference electrode comprising silver chloride of Nankai in the electrochemical biosensor of Bhullar because the accuracy of the measurements obtained can be further improved by incorporating the silver/silver chloride reference electrode, as taught by Nankai (Col. 10, lines 8-10).

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the invention as specified in claim 8.

Regarding claims 17 and 18, Bhullar discloses that the thickness of the middle insulating layer defines the height of the test chamber (Col. 9, lines 26-29).

Bhullar does not disclose expressly what the thickness of the insulating layer is.

Nankai discloses a biosensor, wherein the thickness of said middle insulating layer is between 20 and 400 μm (Col. 5, lines 11-12) or between 50 and 200 μm (Col. 12, lines 43-54).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the middle insulating layer with a thickness between 20 and 400 μm or between 50 and 200 μm of Nankai in the electrochemical biosensor of Bhullar because such a thickness would ensure that only a small sample volume would be necessary for measurement, but in sufficient quantity to ensure high accuracy and rapid response, as taught by Nankai (Col. 2, lines 62-68).

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the inventions as specified in claims 17 and 18.

Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar and Nankai as applied to claim 1 above, and further in view of U.S. Patent Number 6,793,802 to Lee et al., referred to hereafter as "Lee."

Regarding claims 5 and 21, Bhullar (Col. 3, lines 21-24) and Nankai (Fig. 4, **7**, Fig. 8, **7**, Fig. 10, **7**, Fig. 12, **7** and Fig. 13, **7**) disclose a variety of shapes and configurations of the opening in the middle insulating layer and that the volume of sample solution required for analysis is small (Nankai, Col. 2, lines 62-68).

Neither Bhullar nor Nankai disclose expressly that the slot in the middle insulating layer is T-shaped or that the volume of the closed chamber is between 0.5 and 4 μL.

Lee discloses an electrochemical biosensor and a method of making the biosensor (Col. 16, lines 38-50), wherein the slot in the middle insulating layer is T-shaped (Fig. 9B), with a length and width of the opening between 2 and 8 mm and between 0.5 and 5 mm, respectively (Fig. 5A) and the volume of the closed chamber is between 0.5 and 4 μL (Col. 13, lines 43-45).

Bhullar, Nankai and Lee are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute the T-shaped slot in and the small volume of the closed space of the middle insulating layer of Lee in the electrochemical biosensor of Nankai because the T-shape sample area improves the sample application and measuring properties of the biosensor, as taught by Lee (Col. 2, lines 64-66) to ensure a quick and uniform distribution of sample, especially a small volume of sample (Col. 12, lines 38-40).

Therefore, it would have been obvious to combine Bhullar, Nankai and Lee to obtain the inventions as specified in claims 5 and 21.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar and Nankai as applied to claim 1 above, and further in view of U.S. Patent Number 6,299,757 to Feldman et al., referred to hereafter as "Feldman."

Neither Bhullar nor Nankai disclose expressly that the electrochemical biosensor contains a device activation line to automatically activate the measuring device.

Feldman discloses a biosensor with a device activation line or indicator electrode, which can activate the measuring device automatically (Col. 52, lines 14-24).

Bhullar, Nankai and Feldman are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a device activation line or indicator electrode in the electrochemical biosensor of Bhullar because such an indicator would ensure that adequate sample solution has been provided to the sample chamber for accurate and

reliable measurement results, as taught by Feldman (Col. 51, lines 37-41). Automatic activation of the measuring device requires less human input so test results can be obtained faster and without the risk of operator error.

Therefore, it would have been obvious to combine Bhullar, Nankai and Feldman to obtain the invention as specified in claim 23.

Claims 27, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai in view of Bhullar and U.S. Patent Number 6,309,526 to Fujiwara et al., referred to hereafter as "Fujiwara."

Regarding claim 27, Nankai discloses a method of fabricating an electrochemical biosensor (Col. 4, lines 50-51), comprising the steps of:

forming a layer of electrically conductive wires on a substrate by screen-printing (Col. 4, lines 51-57);

forming an electrode layer on top of the layer of electrically conductive wires by screen printing and drying the electrically conductive wires on the substrate and the electrode layer by heating to 100° C (Col. 4, lines 54-57 and 62-63);

forming a middle insulating layer (Col. 4, lines 57-61) with a slot formed therein above said electrode layer, wherein a working electrode, a reference electrode and an

auxiliary electrode are confined within said slot and the opposite ends of said electrodes are exposed to make contact with a measuring device (Col. 5, lines 11-16 and Fig. 4, **8**);

applying an active reaction layer on said slot (Col. 4, line 68-Col. 5, line 5); and

adhering an upper cover formed with an opening therein above the middle insulating layer, wherein said opening is positioned at one end of said slot (Col. 5, lines 6-16),

wherein said slot defines a capillary inflow channel such that a sample of substance can be rapidly introduced into and fill said electrode layer by capillary action upon contact of the substance with a front tip of said capillary inflow channel (Col. 5, lines 19-41 and Col. 12, lines 46-49).

Nankai does not disclose expressly the screen-printed electrically conductive wires are dried before application of the electrode layer or that the method includes the step of applying a surface layer above said upper cover.

Fujiwara discloses a method of fabricating a biosensor comprising the step of forming a layer of electrically conductive wires on a substrate by screen-printing (Col. 1, lines 44-46), wherein drying time is needed after each of the steps of screen-printing (Col. 1, lines 51-55).

Bhullar discloses a method of fabricating an electrochemical biosensor comprising the step of applying a surface cover layer above an upper cover (Col. 9,

lines 36-51) to form a closed chamber above and in communication with a slot (see Fig. 11).

Nankai, Fujiwara and Bhullar are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the step of drying the electrically conductive wires on the substrate of Fujiwara in the method of fabricating a biosensor of Nankai because such a drying step is customary in conventional screen-printing manufacturing methods, as taught by Fujiwara (Col. 1, lines 51-55). It would have been obvious to include the step of applying a surface cover layer above an upper cover to form a closed chamber above and in communication with the slot of Bhullar in the method of fabricating a biosensor of Nankai because the surface cover layer blocks exposure of the reagent/sample mixture to the surrounding environment, as taught by Bhullar (Col. 5, lines 36-40). This protection from contamination would help ensure more accurate and reliable measured results.

Therefore, it would have been obvious to combine Nankai, Fujiwara and Bhullar to obtain the invention as specified in claim 27.

Nankai discloses the limitations of claim 28, wherein the middle insulating layer is formed on top of said electrode layer by screen printing (Col. 5, lines 6-9).

Nankai discloses the limitations of claim 30, wherein the middle insulating layer is formed on top of the electrode layer by adhesion (col. 5, lines 6-11).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai, Bhullar and Fujiwara as applied to claim 27 above, and further in view of Lee.

Nankai (Fig. 4, **7**, Fig. 8, **7**, Fig. 10, **7**, Fig. 12, **7** and Fig. 13, **7**) discloses a variety of shapes and configurations of the opening in the middle insulating layer.

Nankai does not disclose expressly that the slot in the middle insulating layer is T-shaped or that the transverse opening of a T-shaped slot forms two air vents on opposite sides of said biosensor.

Lee discloses a method of making an electrochemical biosensor (Col. 16, lines 38-50), wherein the slot in the middle insulating layer is T-shaped (Fig. 9B) and the transverse opening of said T-shaped slot forms two air vents on opposite sides of a biosensor (Col. 15, line 58-Col. 16, line 5).

Nankai, Bhullar, Fujiwara and Lee are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute the T-shaped slot in the middle insulating layer with two air vents of Lee in the electrochemical biosensor of Nankai because the T-shape sample area improves the sample application and measuring properties of the biosensor, as taught by Lee (Col. 2, lines 64-66) to ensure a quick and uniform distribution of sample (Col. 12, lines 38-40).

Therefore, it would have been obvious to combine Nankai, Bhullar, Fujiwara and Lee to obtain the invention as specified in claim 29.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmv /rmv
July 26, 2005

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